

June 2019

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New drugs

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Emgality [®] (galcanezumab-gnlm) 100 mg/mL solution in a single-dose prefilled syringe Eli Lilly	Calcitonin gene-related peptide antagonist	Treatment of episodic cluster headache in adults and preventive treatment of migraine in adults	June 6, 2019
Kanjinti [™] (trastuzumab-anns) [§] Amgen and Allergan	HER-2/neu receptor antagonist	Adjuvant breast cancer, metastatic breast cancer, and metastatic gastric or gastroesophageal junction adenocarcinoma	TBD
Myxredlin [™] (insulin human in sodium chloride) Celerity Pharmaceuticals	Human insulin	To improve glycemic control in adults and pediatric patients with diabetes mellitus	TBD
Nucala [®] (mepolizumab) single-dose prefilled autoinjector and single-dose prefilled syringe GlaxoSmithKline	IL-5 antagonist monoclonal antibody	Add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype; and treatment of adult patients with eosinophilic granulomatosis with polyangiitis	June 11, 2019
Polivy [™] (polatuzumab vedotin-piiq) ^{†*} Genentech	CD79b-directed antibody–drug conjugate	In combination with bendamustine and a rituximab product, for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified, after at least two prior therapies	June 11, 2019

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Thiola® EC (tiopronin) delayed release tablets Retrophin	Active reducing agent	In combination with high fluid intake, alkali, and diet modification, for the prevention of cystine stone formation in adults and pediatric patients 20 kg and greater with severe homozygous cystinuria, who are not responsive to these measures alone	July 2019
Vyleesi™ (bremelanotide)* AMAG Pharmaceuticals	Melanocortin receptor agonist	Treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder, as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is not due to: a co-existing medical or psychiatric condition, problems with the relationship, or the effects of a medication or drug substance	September 2019
Zirabev™ (bevacizumab-bvzr)*§ Pfizer	Vascular endothelial growth factor inhibitor	Metastatic colorectal cancer, unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, glioblastoma, metastatic renal cell carcinoma, and persistent, recurrent, or metastatic carcinoma of the cervix	TBD

*New molecular entity †Orphan Drug §Biosimilar TBD: To be determined

New generics

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Drug name Manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Diclegis® (doxylamine succinate/pyridoxine) Duchesnay	Teva†, Analog Pharma†, Par†	10 mg/10 mg delayed-release tablet	Treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management	June 21, 2019 ^Δ
Fentora® (fentanyl) Teva	Mayne Pharmaceuticals*	100 mcg, 200 mcg, 400 mcg, 600 mcg, and 800 mcg buccal tablets	Breakthrough pain in cancer patients	June 13, 2019
Naftin® (naftifine) Sebela	Amneal/Tolmar†	1% topical gel	Topical treatment of tinea pedis, tinea cruris, and tinea corporis	June 3, 2019

Drug name Manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Revatio [®] (sildenafil) Pfizer	Novitium Pharmaceuticals [†]	10 mg/mL oral suspension	Pulmonary arterial hypertension	June 3, 2019

[†]A-rated generic manufacturer *Authorized brand alternatives (also known as authorized generic)
^ΔTeva and Analog Pharma launched June 21, 2019; Par TBD

Indications/label updates

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Drug name Manufacturer(s)	Type	Description
Anoro [™] Ellipta [®] (umeclidinium/vilanterol) GlaxoSmithKline	Expanded indication	Maintenance treatment of patients with chronic obstructive pulmonary disease
Biktarvy [®] (bictegravir/emtricitabine/tenofovir alafenamide) Gilead	Expanded indication	As a complete regimen for the treatment of human immunodeficiency virus type 1 infection in adults and pediatric patients weighing at least 25 kg who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically-suppressed on a stable antiretroviral with no history of treatment failure and no known substitutions associated with resistance to the individual components of Biktarvy
Botox [®] (onabotulinumtoxinA) Allergan	Expanded indication	Treatment of upper limb spasticity in pediatric patients 2 to 17 years of age
Darzalex [®] (daratumumab) Janssen	Expanded indication	In combination with Revlimid [®] (lenalidomide) and dexamethasone for the treatment of newly diagnosed multiple myeloma patients who are ineligible for autologous stem cell transplant
Dextenza [®] (dexamethasone) Ocular Therapeutix	Expanded indication	Treatment of ocular inflammation and pain following ophthalmic surgery
Doptelet [®] (avatrombopag) Dova Pharmaceuticals	New indication	Treatment of thrombocytopenia in adults with chronic immune thrombocytopenia who have had an insufficient response to a previous treatment

Dupixent [®] (dupilumab) Regeneron and Sanofi	New indication	Add-on maintenance treatment in adults with inadequately controlled chronic rhinosinusitis with nasal polyposis
Emflaza [®] (deflazacort) PTC Therapeutics	Expanded indication	Treatment of Duchenne muscular dystrophy in patients 2 years of age and older
Emgality [®] (galcanezumab-gnlm) 100 mg/mL Eli Lilly	New Indication	Treatment of episodic cluster headache in adults
Incruse [™] Ellipta [®] (umeclidinium/vilanterol) GlaxoSmithKline	Expanded indication	Maintenance treatment of patients with chronic obstructive pulmonary disease
Inflectra [®] (infliximab-dyyb) Celltrion/Pfizer	Expanded indication	For reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active ulcerative colitis
Keytruda [®] (pembrolizumab) Merck	Expanded indications	In combination with platinum and fluorouracil, for the first-line treatment of patients with metastatic or with unresectable, recurrent head and neck squamous cell carcinoma (HNSCC); and as a single agent, for the first line treatment of patients with metastatic or with unresectable, recurrent HNSCC whose tumors express PD-L1
	New indication	Treatment of patients with metastatic small cell lung cancer with disease progression on or after platinum-based chemotherapy and at least one other prior line of therapy
Mvasi [®] (bevacizumab-awwb) Amgen	Updated indication, Boxed Warning removal	For recurrent glioblastoma in adults The <i>Boxed warning</i> for gastrointestinal perforations, surgery and wound healing complications, and hemorrhage was removed from the drug label
Renflexis [®] (infliximab-abda) Samsung Bioepis	Expanded indication	For reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy
Soliris [®] (eculizumab) Alexion Pharmaceuticals	New indication	Treatment of neuromyelitis optica spectrum disorder in adults who are anti-aquaporin-4 antibody positive

Symdeko[®] (tezacaftor/ivacaftor and ivacaftor) Vertex	Expanded orphan indication	Treatment of patients with cystic fibrosis ages 6 years and older
Victoza[®] (liraglutide) Novo Nordisk	Expanded indication	An adjunct to diet and exercise to improve glycemic control in patients 10 years and older with type 2 diabetes mellitus
Zerbaxa[®] (ceftolozane/tazobactam) Merck	New indication	Treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia

Drug safety news

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Drug name Manufacturer(s)	Description
Zytiga[®] (abiraterone acetate)	The <i>Warning and Precaution</i> section was updated with information regarding risk of QT prolongation and Torsades de Pointes. The section was also updated to include information on increased fractures and mortality in combination with radium Ra 223 dichloride and embryo-fetal toxicity.

Drug recalls/withdrawals/shortages/discontinuations

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Drug name Manufacturer(s)	Dosage form(s)	Type	Description
Fluorouracil Fresenius Kabi	5 g/100 mL (50 mg/mL), 100 mL fill in a 100 mL vial	Recall	Fresenius Kabi announced a voluntary, consumer-level recall of two lots of fluorouracil injection due to the potential for glass particulate. Fluorouracil is a chemotherapy drug that is administered intravenously and indicated for the treatment of a variety of cancers.

Drug name Manufacturer(s)	Dosage form(s)	Type	Description
Flurazepam Mylan	15 mg and 30 mg capsules	Shortage	<p>There is currently a long term drug shortage of flurazepam. Mylan estimates that product will be available in the fourth quarter of 2019. There are no other manufacturers of flurazepam capsules.</p> <p>Flurazepam is indicated for the treatment of insomnia characterized by difficulty in falling asleep, frequent nocturnal awakenings, and/or early morning awakenings.</p>
Gamunex-C® (immune globulin [human]) Grifols Therapeutics	10% (20 gm/200 mL) injection	Withdrawal	<p>Grifols Therapeutics announced a voluntary, consumer-level withdrawal of one lot of Gamunex-C injection due to a higher rate of allergic/hypersensitivity type reactions, a small number of which were considered medically significant.</p> <p>Gamunex-C is indicated for the treatment of primary humoral immunodeficiency in patients two years of age and older; idiopathic thrombocytopenic purpura in adults and children; and chronic inflammatory demyelinating polyneuropathy in adults.</p>
Losartan Teva	50 mg and 100 mg tablets	Recall	<p>Teva recalled several lots of losartan tablets due to the presence of N-Methylnitrosobutyric acid (NMBA) that is above the FDA's interim acceptable exposure limit. Golden State Medical Supply repackaged these products under its own label and distributed retail bottles of 30, 90 and 1000 tablets.</p> <p>Losartan is used for the treatment of hypertension (HTN) and to reduce the risk of stroke in patients with HTN and left ventricular hypertrophy. Losartan is also used for the treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria in patients with type 2 diabetes and a history of HTN.</p>
Losartan-containing products Macleods	Losartan 50 mg tablets Losartan/HCTZ: 50 mg/12.5 mg, 100 mg/12.5 mg and 100 mg/25 mg tablets	Recall	<p>Macleods recalled several lots of losartan-containing tablets due to the presence of NMBA that is above the FDA's interim acceptable exposure limit.</p>

Drug name Manufacturer(s)	Dosage form(s)	Type	Description
MiniMed™ Insulin Pumps Medtronic	Certain MiniMed 508 and MiniMed Paradigm models	Recall	Medtronic MiniMed insulin pumps were recalled to the consumer-level due to potential cybersecurity risks. Insulin pumps are small computerized devices that deliver insulin to a patient throughout the day through a catheter implanted under the skin.
Rescriptor® (delavirdine) ViiV Healthcare	200 mg tablets	Discontinuation	ViiV Healthcare discontinued Rescriptor for business reasons. The discontinuation is not due to any safety, efficacy or quality issues. The anticipated final date for availability is January 2020. Rescriptor is approved for the treatment of human immunodeficiency-1 infection in combination with at least 2 other active antiretroviral agents when therapy is warranted.

Key guideline/literature updates

Topic	Reference
American Academy of Neurology - Treatment of Tics in People with Tourette Syndrome and Chronic Tic Disorders	<i>Neurology</i> . May 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: B-Cell Lymphomas Version – Version 4.2019	<i>NCCN Clinical Practice Guidelines in Oncology: B-Cell Lymphomas Version</i> . June 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Gastric Cancer – Version 2.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Gastric Cancer</i> . June 2019

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Head and Neck Cancers – Version 2.2019	<u>NCCN Clinical Practice Guidelines in Oncology: Head and Neck Cancers.</u> June 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Kidney Cancer – Version 1.2020	<u>NCCN Clinical Practice Guidelines in Oncology: Kidney Cancer.</u> June 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Multiple Myeloma – Version 3.2019	<u>NCCN Clinical Practice Guidelines in Oncology: Multiple Myeloma.</u> June 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer – Version 5.2019	<u>NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer.</u> June 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Uveal Melanoma – Version 1.2019	<u>NCCN Clinical Practice Guidelines in Oncology: Uveal Melanoma.</u> June 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Colorectal Cancer Screening – Version 1.2019	<u>NCCN Clinical Practice Guidelines in Oncology: Colorectal Cancer Screening.</u> June 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Adult Cancer Pain – Version 3.2019	<u>NCCN Clinical Practice Guidelines in Oncology: Adult Cancer Pain.</u> June 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Survivorship – Version 2.2019	<u>NCCN Clinical Practice Guidelines in Oncology: Survivorship.</u> June 2019



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